

**Notice of Allowability**

Application No.

10/736,769

Applicant(s)

ALTMANN ET AL.

Examiner

Art Unit

Samuel W. Liu

1653

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/17/06.
2. ☒ The allowed claim(s) is/are 1,2,50-58,60 and 61.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>8/9/06</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>7/17/06</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                              | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                       |
|   | 9. <input type="checkbox"/> Other _____.   |

### DETAILED ACTION

The amendment filed 7/17/06, which amends claim 50, cancels claims 3-49 and 59, and adds claim 61 has been entered. Pending claims 1-2, 50-58 and 60-61 are examined in this Office action.

The references cited in the IDS filed 7/17/06 have been considered by Examiner.

### EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the change and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Thomas Triolo on August 10, 2006. Applicants agree the Examiner proposed amendment to claims 50-58 and 60-61 (see below).

#### Amendments to the claim:

The pending claims 50-58 and 60-61 have been amended as follows. Please replace the previous claims with the claims shown below.

Claim 50 (*Amended*): A The polypeptide of claim 2 wherein the other polypeptide is selected from the group consisting of a glutathione-s-transferase (GST) tag polypeptide, a hexahistidine tag polypeptide, a maltose binding protein tag, a haemagglutinin polypeptide tag, a cellulose binding protein tag and a myc tag polypeptide.

Claim 51 (*Amended*): A The polypeptide of claim 1 which is labeled with a member selected from the group consisting of  $^{32}\text{P}$ ,  $^{35}\text{S}$ ,  $^3\text{H}$ ,  $^{99\text{m}}\text{Tc}$ ,  $^{123}\text{I}$ ,  $^{111}\text{In}$ ,  $^{68}\text{Ga}$ ,  $^{18}\text{F}$ ,  $^{125}\text{I}$ ,  $^{131}\text{I}$ ,  $^{113\text{m}}\text{In}$ ,  $^{76}\text{Br}$ ,  $^{67}\text{Ga}$ ,  $^{99\text{m}}\text{Tc}$ ,  $^{123}\text{I}$ ,  $^{111}\text{In}$  and  $^{68}\text{Ga}$ .

Claim 52 (*Amended*): A composition comprising the polypeptide of claim 1 ~~which is~~ bound to cholesterol.

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Claim 53 (*Amended*): ~~A polypeptide~~ The composition of claim 52 wherein said cholesterol is radiolabeled.

Claim 54 (*Amended*): ~~A polypeptide~~ The composition of claim 53 wherein the radiolabel is  $^{125}\text{I}$  or  $^3\text{H}$ .

Claim 55 (*Amended*): A composition comprising the polypeptide of claim 1 ~~which is~~ bound to ezetimibe.

Claim 56 (*Amended*): ~~A polypeptide~~ The composition of claim 55 wherein said ezetimibe is radiolabeled.

Claim 57 (*Amended*): ~~A polypeptide~~ The composition of claim 56 wherein the radiolabel is  $^{125}\text{I}$  or  $^3\text{H}$ .

Claim 58 (*Amended*): ~~A polypeptide~~ The composition of claim 55 wherein the ezetimibe is BODIPY labeled ezetimibe.

Claim 60 (*Amended*): A The polypeptide of claim 1 which is glycosylated.

Claim 61 (*Amended*): A The polypeptide of claim 1 which is capable of binding to cholesterol.

**Amendments to the specification:**

In abstract is amended as follows (in one paragraph):

We claim an isolated polypeptide having ability of binding with cholesterol. Said polypeptide is useful for investigating regulation of intestinal cholesterol absorption and cholesterol levels. Also, we claim a composition comprising said polypeptide bound to cholesterol or ezetimibe and a fusion protein comprising the polypeptide thereof.

The following is an **Examiner's Statement of Reasons for Allowance**: According to the agreement set forth in the "Interview Summary" mailed 7/14/06, particularly regarding instant claim 2, Applicants indicate that the claimed polypeptide or fragment thereof is at least useful as antigenic molecule, e.g., raising antibody for detecting the claimed polypeptide or/and analyzing cholesterol levels and regulation of intestinal cholesterol absorption; and thus, fusion of the

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claimed polypeptide to any heterologous polypeptide is within the bounds of enablement.

Examiners agree the above applicants' statement. Therefore, the rejection under 35 USC 112, first paragraph is withdrawn.

Also, Examiners agree to withdraw the rejection under 35 USC 112, second paragraph set forth in the Office action mailed 4/17/06 in light of that the biologically inactive polypeptide can be used for raising antibody for detecting the claimed polypeptide (see the interview summary thereof). Hence, the claims are allowable.

*Conclusion:* claims 1-2, 50-58 and 60-61 are allowed.

Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon, Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval IPAIRI system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAG only. For more information about the PAN system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Samuel W. Liu, Ph.D.  
Patent Examiner, AU1653  
August 10, 2006



KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER

### **Abstract**

We claim an isolated polypeptide having ability of binding with cholesterol. Said polypeptide is useful for investigating regulation of intestinal cholesterol absorption and cholesterol levels. Also, we claim a composition comprising said polypeptide bound to cholesterol or ezetimibe and a fusion protein comprising the polypeptide thereof.